

Claims

- 5 1. A method of assessing the effectiveness of pulmonary drug delivery, comprising the steps of:
- a) providing a drug into an air flow past a sensor comprising a radiation source and a radiation detector;
 - 10 b) detecting, at the radiation detector, incident radiation over a period of time as a measurement profile;
 - c) quantifying at least one characteristic of the shape of a measurement profile; and
 - d) producing an indication of the effectiveness of pulmonary drug delivery based upon the at least one quantified characteristic.
- 15 2. A method as claimed in any preceding claim wherein the indication of the effectiveness of pulmonary drug delivery quantifies the amount of fine particles in the delivered pulmonary drug.
- 20 3. A method as claimed in any preceding claim, wherein the indication of the effectiveness of pulmonary drug delivery is a quantitative measure of the effectiveness of the pulmonary drug delivery.
- 25 4. A method as claimed in claim 1, 2 or 3 for the in-situ assessment of the effectiveness of pulmonary drug delivery, wherein the step of providing a drug involves the release of the drug from a drug delivery device and a breathing simulator provides the air flow.
- 30 5. A method as claimed in claim 1, 2 or 3 for the in-vivo assessment of the effectiveness of pulmonary drug delivery, wherein the step of providing a drug involves the release of the drug from a drug delivery device and the air flow is provided by a person's breath in-take.

6. A method as claimed in any preceding claim, wherein the indication of the effectiveness of pulmonary drug delivery is based upon a single measurement profile.

7. A method as claimed in any one of claims 1 to 5, wherein the indication of the effectiveness of pulmonary drug delivery is based upon a plurality of measurement profiles.

8. A method as claimed in claim 7, comprising the steps of:
repeatedly providing a drug into an air flow past a sensor comprising a radiation source and a radiation detector and detecting, at the radiation detector, incident radiation over a period of time as a measurement profile;
quantifying at least one characteristic of the shape of each of the plurality of detected measurement profiles; and
producing the indication of the effectiveness of pulmonary drug delivery based upon the plurality of at least one quantified characteristics.

9. A method as claimed in claim 7 or 8, wherein the indication of the effectiveness of pulmonary drug delivery includes an average.

10. A method as claimed in claim 7, 8 or 9, wherein the indication of the effectiveness of pulmonary drug delivery includes a measure of the variance in the effectiveness of pulmonary drug delivery.

11. A method as claimed in any preceding claim further comprising the steps of:

assessing the fine particle dose delivered from a first quantified characteristic of the shape of the measurement profile;

assessing the total dose delivered from a second, different, quantified characteristic of the shape of the measurement profile; and

using the assessment of the fine particle dose delivered and the assessment of the total dose delivered to provide an indication of the effectiveness of pulmonary drug delivery.

5 12. A method as claimed in claim 11, wherein the indication of the effectiveness of pulmonary drug delivery is the fine particle fraction of the dose delivered.

10 13. A method as claimed in any one of claims 11 or 12, wherein the first characteristic is the height of the measurement profile or the height of a curve fitted to the measurement profile.

15 14. A method as claimed in any one of claims 11, 12 or 13, wherein the second characteristic involves the normalised integration of the measurement profile over its width or the normalised integration of a curve fitted to the measurement profile over its width.

20 15. A method as claimed in claim 13 or 14, wherein the curve fitted to the measurement profile is a dose function which when summed with a level transition residual function substantially re-creates the measurement profile.

16. A method as claimed in any one of claims 11 to 15, wherein the quantifying and assessment steps occur automatically in situ.

25 17. A method as claimed in any preceding claim further comprising the step of converting the indication of the effectiveness of pulmonary drug delivery based upon the at least one quantified characteristic to a measurement of the effectiveness of pulmonary drug delivery using calibration data.

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18. A method as claimed in any preceding claim wherein steps b), c) and d) occur within a measurement device.

19. A method as claimed in any one of claims 1 to 17, wherein steps a), b), c) and d) occur within a drug delivery device.

5 20. A measurement device for assessing the effectiveness of pulmonary drug delivery, comprising:

a conduit through which air carrying a cloud of drug particles can flow during drug delivery;

a radiation source for providing radiation into the conduit;

10 a radiation detector for detecting radiation from the conduit over a period of time as a measurement profile; and

a processor operable to quantify one or more characteristics of the shape of a measurement profile and to produce an indication of the effectiveness of pulmonary drug delivery based upon the quantified
15 characteristic(s).

21. A measurement device as claimed in claim 20, arranged for releasable attachment to a drug dispensing device.

20 22. A measurement device as claimed in claim 20, integrated within a drug delivery device.

23. A measurement device as claimed in claim 20, 21 or 22, wherein the indication of the effectiveness of pulmonary drug delivery indicates the fine
25 particle component of the delivered pulmonary drug.

24. A measurement device as claimed in any one of claims 20 to 23 further comprising a memory for storing at least one measurement profile.

30 25. A measurement device as claimed in any one of claims 20 to 24, wherein the processor is operable to produce an indication of the

effectiveness of pulmonary drug delivery based upon the quantified characteristic(s) obtained from multiple measurement profiles.

26. A measurement device as claimed in claim 25, wherein the indication
5 of the effectiveness of pulmonary drug delivery includes an average.

27. A measurement device as claimed in claim 25 or 26, wherein the
indication of the effectiveness of pulmonary drug delivery includes a
measurement of variance.
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28. A measurement device as claimed in any one of claims 20 to 27
wherein the indication of the effectiveness of pulmonary drug delivery is a
quantitative indication.

15 29. A measurement device as claimed in any one of claims 20 to 28,
wherein the processor is operable to determine the fine particle dose
delivered from a first quantified characteristic of the shape of a measurement
profile and to determine the total dose delivered from a second quantified
characteristic of the shape of the same measurement profile.

20 30. A measurement device as claimed in claim 29, wherein the processor
is operable to use the determined fine particle dose delivered and the
determined the total dose delivered to calculate an indication of the
effectiveness of pulmonary drug delivery.

25 31. A measurement device as claimed in claim 30, wherein the indication
of the effectiveness of pulmonary drug delivery is the fine particle fraction of
the dose delivered.

30 32. A measurement device as claimed in any one of claims 29 or 31,
wherein the first characteristic is the height of the measurement profile or the
height of a curve fitted to the measurement profile.

33. A measurement device as claimed in any one of claims 29 to 32,
wherein the second characteristic involves the normalised integration of the
measurement profile over its width or the normalised integration of a curve
5 fitted to the measurement profile over its width.

34. A measurement device as claimed in claim 32 or 33, wherein the
processor is operable to fit a dose function curve to a measurement profile,
wherein the summation of the dose function curve with a level transition
10 residual function substantially re-creates the measurement profile.

35. A measurement device as claimed in any one of claims 20 to 34
wherein the operations of the processor are automatic.

15 36. A measurement device as claimed in any one of claims 20 to 34
wherein the operations of the processor are in real-time.

37. A measurement device as claimed in any one of claims 20 to 34
comprising a second radiation detector for detecting radiation from the conduit
20 over a period of time as a second measurement profile, wherein the processor
is operable to produce an indication of the effectiveness of pulmonary drug
delivery based upon a plurality of measurement profiles for a single drug
delivery.

25 38. A measurement device as claimed in claim 37, further comprising a
second radiation source.

39. A method of assessing the effectiveness of pulmonary drug delivery,
comprising the steps of:
30 recording, during a drug delivery, the output of a first radiation detector
against time as a first measurement profile;

recording, during the same drug delivery, the output of a second radiation detector against time as a second measurement profile; and

processing the first and second measurement profiles to produce an indication of the effectiveness of pulmonary drug delivery.

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40. A method as claimed in claim 39, wherein the processing involves a quantitative comparison of the two measurement profiles.

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41. A method as claimed in claim 39, wherein the processing involves the cross-correlation of the two measurement profiles.

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42. A method as claimed in claim 39, 40 or 41, wherein the indication of the effectiveness of pulmonary drug delivery is the speed of a drug cloud during the drug delivery.

43. A method as claimed in any one of claims 39 to 42, wherein the first and second radiation detectors are located at different positions along a drug flow path.

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44. A method as claimed in any one of claims 39 to 42, wherein the first and second radiation detectors are arranged to detect radiation at different energies.

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45. A measurement device for assessing the effectiveness of pulmonary drug delivery, comprising:

a conduit through which air carrying a cloud of drug particles can flow during drug delivery;

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a radiation source for providing radiation into the conduit;

a first radiation detector for detecting radiation from the conduit over a period of time as a first measurement profile;

a second radiation detector for detecting radiation from the conduit over the period of time as a second measurement profile; and

a processor operable to produce an indication of the effectiveness of pulmonary drug delivery based upon the first and second measurement
5 profiles.

46. A drug delivery device for providing a drug dose to a user in a plurality of separate drug deliveries, comprising:

a drug metering means for releasing a controlled amount of drug for
10 each drug delivery;

a conduit through which air carrying a cloud of drug particles can flow;

a radiation source for providing radiation into the conduit;

a first radiation detector for detecting radiation from the conduit during a on-going drug delivery as a first measurement profile; and

15 control means operable to control the drug metering means, for a subsequent drug delivery, in dependence upon at least the first measurement profile.

47. A drug delivery device as claimed in claim 46, wherein the control
20 means is operable to control the drug metering means, for a subsequent drug delivery, in dependence upon an indication of the effectiveness of the on-going drug delivery.

48. A drug delivery device as claimed in claim 47, wherein the indication of
25 the effectiveness of the on-going drug delivery is based upon one or more quantified characteristic(s) of the shape of the measurement profile.

49. A drug delivery device as claimed in claim 47, further comprising a
30 second radiation detector for detecting radiation from the conduit during the on-going drug delivery as a second measurement profile, wherein the indication of the effectiveness of the on-going drug delivery is based upon the first and second measurement profiles.

50. A drug delivery device as claimed in any one of claims 46 to 49, wherein the drug metering means is arranged to vary the amount of drug released in a subsequent drug delivery, in dependence upon at least the first measurement profile.

51. A drug delivery device as claimed in any one of claims 46 to 50, wherein the drug metering means is arranged to vary the number of drug deliveries required in dependence upon at least the first measurement profile.

52. A method of assessing the effectiveness of fine particle delivery, comprising the steps of:

a) providing an air flow comprising particles past a sensor comprising a radiation source and a radiation detector;

b) detecting, at the radiation detector, incident radiation over a period of time as a measurement profile;

c) quantifying at least one characteristic of the shape of a measurement profile; and

d) producing an indication of the effectiveness of fine particle delivery based upon the at least one quantified characteristic.

53. A method, device or system substantially as hereinbefore described with reference to and/or as shown in the accompanying drawings.

54. Any novel subject matter or combination including novel subject matter disclosed, whether or not within the scope of or relating to the same invention as the preceding claims.